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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,265	12/03/2001	Masatsugu Maeda	14875-096001/C2-105DP1P	5055
26161 7590 03/22/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER WEHBE, ANNE MARIE SABRINA	
			ART UNIT	PAPER NUMBER
			1633	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/006,265

Applicant(s)

MAEDA ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 and 28-31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,5,7 and 20-23 is/are allowed.
- 6) ☒ Claim(s) 2,4,6,8 and 24-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment and response received on 1/5/07 have been entered. Claims 1-31 are pending in the instant application. Claims 9-19 and 28-31 remain withdrawn from consideration as being drawn to an invention non-elected without traverse in the paper filed on 1/10/05. Claims 1-8, and 20-27 are currently under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

#### ***Claim Rejections - 35 USC § 112***

The rejections of claims 5-7, 22-23, and 27 under 35 U.S.C. 112, second paragraph, for indefiniteness are withdrawn in view of applicant's amendments to the claims.

The rejection of claims 24-27 under 35 U.S.C. 112, first paragraph, for lack of enablement is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the rejection for reasons of record as discussed in detail below.

The applicant argues that not everything necessary to the practice of the invention need be disclosed in the specification, and that what is well known may be omitted, citing *In re Wright* and *In re Buchner*. Accordingly, the applicant argues that the prior art teaches, as exemplified by Bowie et al., that many point mutations can be made in a protein which are silent, and that it

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would not be undue experimentation to identify those single amino acid substitutions that do not affect protein functionality. In addition, the applicant argues that since the claimed protein sequences are members of the hematopoietic-factor-binding family, several conserved domains specific to this family are known, citing Dillon et al., Diveu et al., and Kernebeck et al., and therefore the skilled artisan would know to avoid making changes in these domains.

In response, while the Bowie et al. reference teaches that many residues in the Lac repressor protein tolerate substitutions without losing function, Bowie et al. further teaches regarding families of proteins that. “[f]unctionally important residues should be conserved in sets of active sequences, but it is not possible to decide whether a side chain is functionally or structurally important just because it is invariant or conserved. To make this distinction requires an independent assay of protein folding” (Bowie et al., page 1308). Bowie et al. further teaches that the ability to fold correctly, while one parameter of judging the effects of substitutions, does not indicate functionality as mutant proteins may form a stable structure and be inactive. Therefore, Bowie et al. teaches that both folding and functionality must be tested (Bowie et al., page 1308). However, since the ligand for the proteins comprising the amino acid sequence of SEQ ID NOS: 2, 4, or 17 have not been identified, the specification lacks sufficient guidance for determining which single amino acid substitution mutants of these sequences are in fact functional. To say that simply avoiding conserved residues should result in a functional protein is contrary to the teachings of Bowie, who teaches that it is not possible without direct experimentation to determine whether even an invariant or conserved residue is functionally or structurally important. Thus, since an assay for functionality of the claimed sequences is lacking,

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it would require undue experimentation to identify functional mutants of SEQ ID NOS 2, 4, and 17 as claimed.

***Claim Rejections - 35 USC § 102***

The rejection of claims 2, 4, 6, and 8 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,642,360 (11/4/03), hereafter referred to as Filvaroff et al., is withdrawn in view of applicant's amendment to the claims.

Applicant's amendment has necessitated the following new grounds of rejection under 35 U.S.C. 102(e).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 4, 6, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by 6,747,137 (2004), hereafter referred to as Weinstock et al. The applicant claims an isolated nucleic acid comprising a nucleotide sequence encoding a fragment of an amino acid sequence of SEQ ID NO:2, 4, or 17, wherein the fragment is at least 7 amino acids in length, a vector

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comprising the nucleic acid, and a transformant harboring the nucleic acid or vector comprising the nucleic acid.

Weinstock et al teaches an isolated nucleic acid sequence comprising a fragment with 100% sequence identity to a 9 amino acid fragment of SEQ ID NO:17 (Weinstock et al., SEQ ID NO: 3111). Weinstock et al. further teaches vectors comprising the isolated nucleic acid, and host cells transformed with the vector comprising the nucleic acid (Weinstock et al., columns 7-8). Thus, by teaching all the limitations of the claims as written, Weinstock et al. anticipates the instant invention as claimed.

***Allowable Subject Matter***

Claims 1, 3, 5, 7, and 20-23 are considered free of the prior art and allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

